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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/532,278	04/21/2005	Gabrio Roncucci	M1100.70002US00	8497

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EXAMINER	
WARD, PAUL V	

ART UNIT	PAPER NUMBER
1624	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/532,278	RONCUCCI ET AL.	
	Examiner	Art Unit	
	PAUL V. WARD	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 March 2010*.

2a)☒ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4,5,7,8,10,19,20 and 23-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *1,2,4,5,10,23 and 25-28* is/are allowed.

6)☒ Claim(s) *7,8,19,20,24 and 29-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

STATUS OF THE CLAIMS: Claims 1-2, 4-5, 7-8, 10, 19-20, and 23-34.

Response to Arguments Regarding

Claim Rejections - 35 USC § 112, 2nd paragraph and § 102

1. The rejections, of claims 1-10, have been overcome by Applicant's amendment in the reply filed September 8, 2006.

Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

2. Claims 7-8 and 29-34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 7-8 and 29-34 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01.

Claim Rejections - 35 USC § 112, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 19-20 and 24 are directed to a method of treating viral, fungal, bacterial diseases characterized by cellular hyperproliferation and dermatological diseases including cellular hyperproliferation, psoriasis, intimal hyperplasia, benign prostate

hyperplasia and athromas. The terms are interpreted to include any and all forms of viral, fungal, bacterial diseases characterized by cellular hyperproliferation and dermatological diseases. In light of this, it can be asserted that in spite of the vast expenditure of human and capital resources in recent years, no one drug has been found which is effective in treating all types of wounds and treating viral, fungal, bacterial diseases characterized by cellular hyperproliferation and dermatological diseases. In re Hokum, 226 USPQ 353 (ComrPats 1985).

The determination that "undue experimentation" would have been needed to make and use the claimed invention is not a single, simple factual determination. Rather, it is a conclusion reached by weighing all the above noted factual considerations. In re Wands, 858 F.2d at 737, 8 USPQ2d at 1404.

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue". These factors include, but are not limited to:

(A) The breadth of the claims;
(B) The nature of the invention;
(C) The state of the prior art;
(D) The level of one of ordinary skill;
(E) The level of predictability in the art;
(F) The amount of direction provided by the inventor;
(G) The existence of working examples; and
(H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

The breadth of the claims

The breadth of the instant claims is seen to encompass methods for treating viral, fungal, bacterial diseases characterized by cellular hyperproliferation and dermatological diseases by administering to a patient in need of such treatment a therapeutically effective amount of the compound claim. Applicant failed to exactly define what types of wounds and treating viral, fungal, bacterial diseases characterized by cellular hyperproliferation and dermatological diseases are treated. Thus, the claims are extremely broad.

The nature of the invention

The nature of the invention is the treatment of treating viral, fungal, bacterial diseases characterized by cellular hyperproliferation and dermatological diseases through the use of the claimed compound and derivatives thereof. Currently, there are no known agents that treat these diseases all inclusively.

The level of predictability in the art

The treatment of viral, fungal, bacterial diseases characterized by cellular hyperproliferation and dermatological diseases is highly unpredictable. It is well established that "the scope of enablement varies inversely with the degree of unpredictability of the factors involved," and physiological activity is generally considered to be an unpredictable factor. See In re Fisher, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970).

The amount of direction provided by the inventor.

The applicant has not demonstrated sufficient guidance provided in the form of administration profiles, combination ratios of the active agents or reference to the same in the prior art to provide a skilled artisan with sufficient guidance to practice the instant treatment of wounds and treating viral, fungal, bacterial diseases characterized by cellular hyperproliferation and dermatological diseases claimed. Further, the applicant discloses that an effective amount of the compound will be administered without providing any direction other than that the compounds of the invention have a high therapeutic index and follows this with a definition readily found in a basic pharmacology textbook. It should be noted that the therapeutic index of a drug in humans is almost never known and is only determined through clinical experience.

The existence of working examples.

There is not seen in the disclosure, sufficient evidence to support Applicant's claims of treating viral, fungal, bacterial diseases characterized by cellular hyperproliferation and dermatological diseases. A conclusion of lack of enablement means that, based on the evidence regarding each of the above factors, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation. In re Wright, 27 USPQ2d 1510 (CAFC). The disclosure does not demonstrate sufficient evidence to support the applicant's claim to the treatment and methods in inhibition. There are not sufficient working examples or data from references of the prior art to provide a nexus between those examples and a method of treating

viral, fungal, bacterial diseases characterized by cellular hyperproliferation and dermatological diseases with the claimed compound.

The level of one of ordinary skill.

The level of skill is that of one with a doctoral understanding of viral, fungal, bacterial diseases characterized by cellular hyperproliferation and dermatological disease therapeutics. Applicant's data is not convincing as to make the production and use of pharmaceutical compositions comprising the recited compounds feasible without undue, un-predictable experimentation.

The quantity of experimentation.

A great deal of experimentation is required. In order for there to be a method of treating viral, fungal, bacterial diseases characterized by cellular hyperproliferation and dermatological diseases generally, as claimed by the applicant, it would be necessary to show that a vast range of different types of viral, fungal, bacterial diseases characterized by cellular hyperproliferation and dermatological diseases. Furthermore, direction, in the form of examples, must be shown to determine what an effective dose may be. The references submitted do not demonstrate this. Therefore, one of ordinary skill in the art would require a significant amount of experimentation in order to determine the effective dosage to treat the multitudes of different types of viral, fungal, bacterial diseases characterized by cellular hyperproliferation and dermatological diseases with the claimed compound individually or in combination with other therapeutic agents.

Thus, it can be safely concluded that the instant case fails to provide an enabling disclosure for the treatment viral, fungal, bacterial diseases characterized by cellular hyperproliferation and dermatological diseases.

Allowable Subject Matter

Claims 1-2, 4-5, 10, 23 and 25-28 are allowed. The compounds, compositions and method of sterilizing in Claims 1-2, 4-5, 10, 23 and 25-28 were not found to be obvious nor anticipated by the prior art of record. Thus, the prior art does not teach or suggest the presently claimed compounds. Therefore, these claims will be allowed if amended to overcome a rejection under 35 USC 112.

Conclusion

Claims 1-2, 4-5, 7-8, 10, 19-20, and 23-34 are pending. Claims 7-8, 19-20, 24 and 29-34 are rejected. Claims 1-2, 4-5, 10, 23 and 25-28 are allowed

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PAUL V WARD whose telephone number is 571-272-2909. The examiner can normally be reached on M-F 8 am to 4 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0642. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/PAUL V WARD/
Examiner, Art Unit 1624